

-- 33. (NEW) The implant of Claim 28 further including a plurality of nano-scale ceramic layers independently forming a hardness-imparting ceramic module and a toughness-imparting module. --

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**REMARKS**

In the Office Action, the Examiner noted that Claims 1-30 are pending in the application of which Claims 1-30 are rejected; but that Claims 9, 10, and 21-27 would be allowable if rewritten to overcome particular rejections.

By the present amendment, Claims 2-7, 14-17, and 28 have been amended, and New Claims 31-33 have been added; thus, Claims 1-33 are pending in the application. The Examiner's rejections are traversed below.

**Response to Paragraph 1 of the Office Action**

**Objection to Specification**

In the Office Action the Examiner objected to the specification because of certain informalities. By the present amendment, the specification has been amended. Applicants submit that these amendments obviate the objections.

**Response to Paragraph 2 of the Office Action Examiner's**

**Objection to Claims**

In the Office Action the Examiner objected to the claims because of certain informalities. By the present amendment, the claims has been amended. Applicants submit that these amendments obviate the objections.

**Response to Examiner's Claim Rejection – Paragraph 3**

**Under 35 U.S.C. § 112 second paragraph**

In the Office Action the Examiner rejected Claims 1-30 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention.

As to the rejections regarding Claims 3, 14, 15, and 16, by the present amendment, said claims have been amended to more particularly point out and distinctly claim the subject matter. Applicants respectfully submit that amendments obviate the rejection.

As to the rejection regarding Claim 1, the Examiner stated that the phrase "'formed of" implies unknown process limitations and renders the claim indefinite.'

Applicants respectfully disagree with the Examiner. The phrase "formed of" refers to the state of the coating as is claimed. The Applicants' use of the term "of" is consistent with the definition provided in Webster's Ninth New Collegiate Dictionary. (see the highlighted attached page from the dictionary under the heading "of", sense number 3).

Applicants request the withdrawal of this rejection.

As to the rejection regarding Claim 6 and/or 5, the Examiner stated that 'claim 5 should state "the group consisting of aluminum, zirconium, or hafnium compounds."

By the present amendment, Applicants have amended Claims 5 and 6. In particular, Claim 5 as amended recites, in part: "... from the group consisting of

alumina, zirconia and hafnia containing components."

Claim 6, as amended recites, in part: "...water swellable ceramic material is a nitride of material selected from the group consisting of alumina, zirconia, and hafnia.

As to the rejection regarding Claims 9, 10, 17, 18, 21, and 27, the Examiner stated that "It is unclear as to whether the zirconia and alumina are in the same layer and the bilayer is multiple layers of this dual compositional layer or if the bilayer is alternating alumina and zirconia.

Applicants respectfully disagree with the Examiner. According to Webster's Ninth New Collegiate Dictionary, bilayer is defined as a "film or membrane with two molecular layers." Furthermore, the Applicants have defined the term bilayer in the application as originally filed. As such, Applicants do not believe that the term as used in said claims is unclear and respectfully request withdrawal of the rejection.

#### **Response to Paragraphs 6-7 of the Office Action**

##### **Claim Rejection Under 35 U.S.C §102**

In the Office Action, the Examiner, rejected Claims 1-6, 11, 12, 17, 18, and 28 under 35 U.S.C. §102(b) as being unpatentable over Schulz et al. (US Patent No. 5,246,787), stating that "Schulz et al., teach an instrument with a wear resistant hard coating for working or processing organic material and is also suitable as implants for the human body including a basic steel body, a transition layer, a separating layer, and a hard coating layer. The hard coating layer may be TiN, or compounds of nitrogen with zirconium or hafnium or mixtures thereof. The

separating layer is aluminum oxide or may be an oxide of titanium, zirconium, or hafnium or mixtures thereof. The transition layer gradually changes from aluminum at the surface of the body to aluminum oxide at the surface of the intermediate layer. The separating and transition layers provide a plurality of ceramic bilayers between the body and the hard coating."

Schulz et al., teaches a coated tool or instrument has a wear-resistant hard coating (7) which is preferably titanium nitride for working organic material which is disposed on a separating layer (9) applied on a basic body (3). The separating layer (9) comprises an amorphous ceramic electrically non-conducting material. Such a material is preferably an oxide, nitride or oxynitride of silicon. The separating layer (9) protects the basic body (3) of the tool or instrument of e.g. a non-corrosion resistant steel. The hard coating (7) and the separating layer (9) having, respectively, a thickness of about 3 micron and 0.5-5 microns.

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." W.L. Gore & Associates v. Garlock, Inc., 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

Claim 1, recites, in part: "... a protective coating ... comprising ... an outer layer formed of water swellable ceramic material."

Schulz et al. does not teach or suggest a coating including an outer layer of water-swellable ceramic material. In fact, the only reference to the outer coating (7) in Schulz et al. is that the layer (7) is a wear-resistant hard coating.

Applicants respectfully submit that Claim 1, is not anticipated by or obvious

in view of Schulz et al.; and that the present said claims are patently distinguishable over the same. Applicants respectfully request withdrawal of this rejection and the allowance of Claims 1 and all those depending directly or indirectly therefrom.

Amended Claim 17, recites in part: "A nanostructure protective coating ... including at least one bilayer formed of different material selected from ...."

Schulz et al. does not teach or suggest a nanostructure protective coating for a substrate, the coating comprising a plurality of nano-scale ceramic layers including at least one bilayer formed of different material selected from selected from the group consisting of zirconia, titania, alumina, and aluminum nitride."

Applicants respectfully submit that Claim 17, is not anticipated by or obvious in view of Schulz et al.; and that the present said claims are patently distinguishable over the same. Applicants respectfully request withdrawal of this rejection and the allowance of Claim 17.

Claim 18, as presently amended, recites in part: "A nanostructure protective coating for a substrate, the coating comprising an outermost coating layer comprising a compound capable of forming a hydrate or hydroxide compound upon contact with an oxygen containing environment ... ."

Schulz et al. does not teach or suggest a nanostructure protective coating comprising an outermost coating layer comprising a compound capable of forming a hydrate or hydroxide compound upon contact with an oxygen containing environment.

Applicants respectfully submit that Claim 18, is not anticipated by or obvious in view of Schulz et al.; and that the present said claims are patently distinguishable over the same. Applicants respectfully request withdrawal of this rejection and the allowance of Claim 18.

Claim 28, as presently amended recites, in part: "[an] intracorporeal implant, ... a protective coating thereon which has an outermost coating layer comprising a compound capable of forming a hydrate or hydroxide compound upon contact with an oxygen containing environment."

Schulz et al. does not teach or suggest an implant having a protective coating comprising an outermost coating layer comprising a compound capable of forming a hydrate or hydroxide compound upon contact with an oxygen containing environment.

Applicants respectfully submit that Claim 28, is not anticipated by or obvious in view of Schulz et al.; and that the present said claims are patently distinguishable over the same. Applicants respectfully request withdrawal of this rejection and the allowance of Claim 28.

#### **Response to Paragraphs 8-10 of the Office Action**

#### **Claim Rejection Under 35 U.S.C. § 103**

In the Office Action the Examiner rejected Claims 7, 8, and 13-16 under 35 U.S.C. § 103 as being unpatentable over Schulz et al. (US 5,246,787) in view of Armini et al. (US 5,674,293) and rejected Claims 19, 20, 29, and 30 as being

upatentable over Schulz et al. (US 5,246,787) in view of Davidas (US 4,326,305).

Applicants respectfully submit that Claims 7, 8, 13-16 and 19, 20, 29, 30 are patentably distinguishable over Schulz et al. and over Schulz et al. in view of Armini et al. or Davidas, at least as claims depending directly or indirectly from Claim 1; and request the withdrawal of the rejection and allowance of the claims.

#### **Response to Paragraphs 11-13 of the Office Action**

##### **Allowable Subject Matter**

Applicants note with appreciation the indication that "claims 9 and 10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this office action and to include all of the limitations of the base claim and any intervening claims."

##### **Additional Remarks**

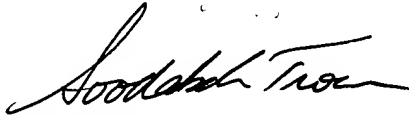
By the present amendment New Claims 31-33 has been added. Applicant submits that new Claims 31-33 meet the requirements of 35 U.S.C. § 112 and that they defines patentable subject matter. Applicant further submits that new Claims 31-33 are not anticipated by or obvious in view of Schulz et al., alone or in combination with Armini et al., or Davidas, and respectfully requests the allowance of the same.

Support for this amendment can be found in the application (specification and drawings), in particular the drawings, as originally filed.

Applicants wish to bring to the attention of the Examiner the enclosed pages from the Webster 's Ninth New Collegiate Dictionary including: including: front cover, inside cover, page 149, noting the highlighted definition of "bilayer."

Applicants submit that the claims as amended define patentable subject matter and respectfully request reconsideration and early allowance.

Respectfully submitted,



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